

RESPONSE**1. INCOMPLETE AMENDMENT**

The previous amendments were not proofread with sufficient care, and it is regretted that the pre-correction spelling and appropriate underlining/bracketing was missing in several paragraphs. The amendments to the specification have been reviewed and placed in proper form, and, on the assumption that none were entered, all of them have been re-submitted. An amendment to paragraph 0063 is newly submitted. All are now listed by paragraph number only, to eliminate ambiguity, and all contain both the replacement words underlined, and the former words in strikethrough or in brackets. Each correction in the specification is for the correction of obvious typographical errors, and no change in scope is intended, or believed to have been made. (Please note that the error in paragraph 0065 is visible in the text version on the USPTO web site, but does not appear in the .pdf file of the publication.) It is believed that the amendments to the specification are now fit for entry into the case. No additional amendments to the claims are submitted.

1. REJECTIONS UNDER 35 USC Sect 112

Claims 1 (and dependents) and 30 are rejected under USC 112 for lack of basis in the specification, subsequent to the addition of "about" to certain ranges in these claims. It is believed that support for the ranges being "soft" exists in the specification and original claims. Paragraph [0065] at its ninth line reads "...a range of about 10% and 30%..." [of propylene oxide monomers], as did original claim 4, which can reasonably be read as support for the amendment. In claim 30, the values (75% EO/ 25% PO) are within the "about 10 to 30%" range, and so are appropriately approximate rather than rigid.

However, because there is normally some range available to a numeric value even without an "about", and in the interest of obtaining allowance of the claims, applicant invites Examiner, as part of a notice of allowance, to remove the "about"s in question as an Examiner's amendment restoring the language of the original claims and not affecting their scope.

4. REJECTIONS UNDER 35 USC 102

Claims 1 - 3 and 8 remain rejected under 102b as anticipated by Muller et al, US 5,624,972. It appears from Examiner's remarks that applicant's characterization of the difference between Muller et al and applicants claims, as made in the previous response, were not sufficiently clear.

The quotation on p 19 of applicant's application (as filed; paragraph 45 as published) is meant to convey that there are major differences in the way the word "hydrophilic" is used in the literature. Applicant does not feel that a low EO (ethylene oxide) content is useable in the invention, and accordingly claims about 70% or more of EO. This is a distinguishing feature over Muller et al.

Muller et al want to make a low-density PU (polyurethane) foam for cushions and the like (col. 1/line 10-18) without using the banned ozone-destroying chlorofluorocarbons (2/34-46). The composition uses "crude" MDI (3/2; detail through 3/33), some of which is reacted with a polyol prepolymer. Mixtures with TDI are allowed (4/9). Polyether polyols may be made by "adding PO to a glycol" (4/26- 28).

The list of useable polymers is predominantly hydrophobic, as listed at 4/46-52. Muller et al's polyether/polyols are described at 4/53 - 5/11. It is here that the "10:80%" polyethylene oxide content is mentioned. The next line mentions 30%, more preferably 25% , as the upper EO percentage, and this agrees with the rest of the compositions in Muller et al, and with how they are used.

In the Glossary, a composition is described ("E"; 9/60 - 10/3) with 75% EO: 25%PO (9/67), but it is mixed with about three times the weight of a 87:13 PO:EO polyol, giving an overall EO content of 28%. Likewise, "F" has overall 10.9% EO by "tipping" (10/8-10). Preparation A is described as "tipped" and is presumably similar in EO content. Preparation D is made from A.

Muller et al's Examples use the prepolymers of the Glossary (A, D, F) or a non-described commercial material, in each case containing large amounts of unreacted diisocyanates, to make foams by reaction with 2 - 4% water.

None of these compounds is hydrophilic enough for use on human tissue. The hydrophobic materials of Muller et al require vigorous mixing with water to react and foam (9/3-18). As described in Applicant's paragraphs 0045 and 0046, applicants considered the functional use of similar materials as a basis for tissue adhesives, and

found, based on experiments using a polyurethane with about 50% propylene oxide and 50% ethylene oxide, among others, that it would not bond to tissue, but polymerized to form a non-attached material. (This information was not made into an Example, but could be submitted as an affidavit if required.) In contrast, applicant's hydrophilic materials containing above about 70% EO do bond well to tissues.

Moreover, Muller et al teaches the manufacture of a foam. In addition to being hydrophobic, when Muller's polyols are exposed to water, the resulting product is a polyurethane foam and not a tissue bond.

Because Muller et al do not teach a tissue bonding material, or an adhesive material, but instead teaches a foam; and also because the Muller reference uses only a material containing a majority of hydrophobic monomer units, while applicants explicitly claims a significant majority of hydrophilic monomer units precisely because a majority of hydrophobic units doesn't adhere well to tissue, the pending rejection under Section 102 is respectfully traversed.

5. REJECTIONS UNDER 35 USC 103

All of the rest of the claims - 4-7, 9-14, 17 - 30, and 40 - 49 - are rejected as being obvious over Muller et al. This rejection is respectfully traversed for the same reasons as the 102 rejections were traversed, i.e., that the Mueller materials are used to make a different product, and that Applicants know that materials of the particular character used by Mueller are not useful as tissue adhesives. Because of the non-functionality of the Muller et al polymers in the application, they could not lead a person to make a biocompatible tissue-bonding adhesive from them, since trying to use the materials of the examples of Muller to make a tissue adhesive would fail.

Thus, dependent claims 4 - 14, less 8, which depend on claim 1 and recite its limitations as well as further limitations, should be allowable for exactly the same reasons.

Independent claim 17 describes a bioadhesive comprising branched copolymers of both of two types, one type of less than about 10% PO and the other in the range of about 10% to 30% PO. Claims 18 - 30 depend on claim 17. These biocompatible adhesive compositions likewise contain polymers fall into the same range of EO and PO

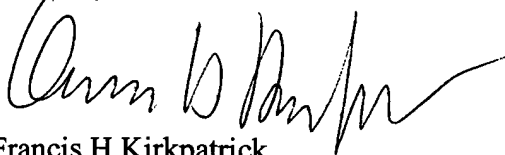
contents as do those of claim 1, and likewise should be allowable. Moreover, Muller neither clearly teaches nor motivates the use of branching polymers, which is not surprising because most commercial PU foam is not crosslinked.

Independent claim 40 describes a biocompatible tissue-bonding preparation comprising at least one N-functional polymer terminated with isocyanate, and with about (N-1)% of free isocyanate in the solution, wherein the composition is essentially anhydrous at the time of its application to tissues. Because Muller's composition is not finished until it is mixed with water, it does not reasonable make applicant's composition obvious. Moreover, Mueller et al uses large excesses of free isocyanate in making foam, comprising upwards of 20% in the examples presented, further teaching away from applicant's materials. Claim 44 depends on claim 40 and contains the further limitation of 10% to 30% propylene oxide. Claim 45 adds the limitation of reciting the tissue reaction. None of these claims can be obvious over Muller, because Muller's polymers will not work, and because Muller's process adds water to hydrophobic polyurethane prepolymer to make a foam, rather than to tissue for forming a tissue adhesive.

In conclusion, it is believed that the amendments have been placed in proper form; that the 112 issues have been obviated; and that the 102 and 103 rejections are inapplicable to the claims as presently pending. Passage of claims 1 - 14, 17 - 30 and 40 - 49 to issue is respectfully requested.

If an interview can assist in any way in furthering prosecution, the Examiner is encouraged to contact the undersigned at cell phone 978-7990-7186; fax 978-256-3679; or at fckirk@comcast.net. It is believed that no fee is due with this submission, but should a fee be due, please debit my deposit account 50-3300 to pay it.

Sincerely,



Francis H Kirkpatrick

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